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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,930	11/09/2001	Achim Harder	Mo-6752/LeA 33,583	5556

7590

08/04/2003

BAYER PHARMACEUTICALS CORP
400 MORGAN LAND
WEST HAVEN, CT 06516-4175

EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,930

Applicant(s)

HARDER ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 3-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 7-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 3-6 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 2 sheets
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicants' amendment filed May 8, 2003 is acknowledged and has been entered. Claims 1 and 3-10 have been amended. Claims 1-10 are pending in the present application.
2. Applicant's election of Group I, claims 1, 2 and 4-10 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that although claims 4-6 are a part of the elected invention, they do not correspond to the elected species with regard to the R groups on the cyclic depsipeptide. Specifically, R³, R⁷, R⁴, R⁸ and R¹⁰ are not defined as elected in claims 4-6. The formula I, cyclic depsipeptide, will be examined (112,1 enablement issues and prior art search) using the structure set forth in the specification on page 24. Claims 1, 2 and 7-10 will be examined in the pending application.
3. Claims 3-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.
4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. However, Applicants have not filed an English translation of these priority documents (PCT/EP00/04014 and

Germany 19921887.0). The effective filing date of the present application is November 9, 2001.

Applicant cannot rely upon the foreign priority papers to overcome any prior art rejections because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by von Samson-Himmelstjerna et al (European J. Neuroscience, 2000, 12/Suppl.11:43).

The claims are directed to an endoparasitocidal composition comprising piperazines together with cyclic depsipeptides consisting of amino acids and hydroxycarboxylic acids as ring units and having 24 ring atoms, and a method for increasing the endoparasitocidal action of cyclic depsipeptides comprising contacting the endoparasites with the composition.

von Samson-Himmelstjerna et al discloses cyclic depsipeptides (PF 1022A and Bay 44-4400) and that these compounds stimulate the GABAergic neurotransmission and simultaneously inhibits the cholinergic system. The prior art discloses the effects of Bay 44-4400 in the presence of the well-known GABA

agonist piperazine against different mouse nematodes. A synergistic effect between Bay 44-4400 and piperazine was observed due to an increased anthelmintic in vitro activity against *T. spiralis* larvae, to an accelerated worm expulsion of *H. polygyrus* or *H. spumosa* from the intestines of infected mice and to a significantly higher degree of degenerating effects of the intestine and on the nerve cord of *H. spumosa* compared to the effects of the single compounds (see abstract).

The prior art discloses the claimed invention. The compositions of the prior appear to be the same or an obvious or analogous variant. The methods appear to have the same result as claimed by Applicants. Since the Patent Office does not have the facilities for examining and comparing applicants' composition and method with the composition and method of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed composition and method and the composition and method of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. Claims 1, 2 and 7-10 are rejected under 35 U.S.C. 102(a or b) as being anticipated by Nicolay et al (Parasitol. Res., 2000, 86:982-992).

Nicolay et al discloses a study of the synergistic effects on cyclic depsipeptide and piperazine in the treatment against nematodes (abstract, p. 982; figures 2-4). Nicolay et al discloses that an additive effect was observed, piperazine alone exerted an efficacy of 54.4% and cyclic depsipeptide alone exerted an efficacy of 44.4%, whereas the combination of these compounds had an efficacy of 97.5% (abstract; materials and methods, figures 2-4, table 1).

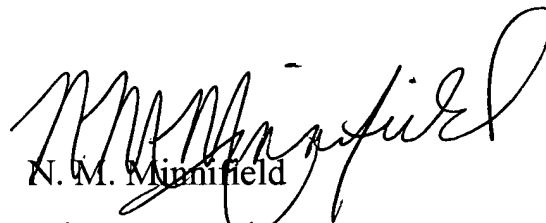
The prior art discloses the claimed invention. The compositions of the prior appear to be the same or an obvious or analogous variant. The methods appear to have the same result as claimed by Applicants. Since the Patent Office does not have the facilities for examining and comparing applicants' composition and method with the composition and method of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed composition and method and the composition and method of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. No claims are allowed.
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'N. M. Minnifield', written in a cursive style.

N. M. Minnifield

Primary Examiner

Art Unit 1645

NMM

July 23, 2003